IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY LIMITED, a Japanese Corporation, and TAP PHARMACEUTICAL PRODUCTS INC., a Delaware Corporation,	)	
Plaintiffs,	)	C.A. No. 08-339-SLR
v.	)	
BARR LABORATORIES, INC., a Delaware Corporation, and BARR PHARMACEUTICALS, INC., a Delaware Corporation,	)	
Defendants.	)	

ANSWER OF DEFENDANTS BARR LABORATORIES, INC. AND BARR PHARMACEUTICALS, INC. AND COUNTERCLAIM BY BARR LABORATORIES, INC.

Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively "Barr"), Answer the Complaint of Takeda Pharmaceutical Company Limited ("Takeda") and TAP Pharmaceutical Products, Inc. ("TAP") (collectively "Plaintiffs" or "Counterdefendants") as follows:

1. Upon information and belief, based on the allegations of the Complaint, Barr admits that Takeda Pharmaceutical Company Limited is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan. Barr lacks sufficient knowledge to form a belief as to the truth of the remaining allegations of Paragraph 1 of the Complaint, and therefore denies them.

2. Upon information and belief, based on the allegations of the Complaint, Barr admits that TAP Pharmaceutical Products Inc. ("TAP") is a Delaware corporation, having a principal place of business at 675 North Field Drive, Lake Forest, Illinois. Barr lacks sufficient

knowledge to form a belief as to the truth of the remaining allegations of Paragraph 1 of the Complaint, and therefore denies them.

3. Barr admits that Barr Pharmaceuticals, Inc. is a Delaware corporation. Barr denies the remaining allegations of paragraph 3 of the Complaint.

4. Barr admits that Barr Laboratories, Inc. is a Delaware corporation with a place of business in Pomona, New York. Barr denies the remaining allegations of paragraph 4 of the Complaint.

5. Barr admits that Barr Laboratories, Inc. is a wholly-owned subsidiary of Barr Pharmaceuticals, Inc. Barr denies the remaining allegations of paragraph 5 of the Complaint.

6. Barr denies the allegations of paragraph 6 of the Complaint.

7. Barr admits that Barr Pharmaceuticals, Inc. owns its subsidiary, Barr Laboratories, Inc., which conducts operations in the United States. Barr denies the remaining allegations of paragraph 7 of the Complaint.

8. The allegations of paragraph 8 of the Complaint state a legal conclusion to which no response is required. Barr admits that Plaintiffs purport to base their Complaint upon the patent laws of the United States of America, Title 35, United States Code and subject matter jurisdiction on 28 U.S.C. §§1331 and 1338(a). Barr denies the remaining allegations of paragraph 8 of the Complaint.

9. Barr does not contest in this action that this Court has personal jurisdiction over Barr Pharmaceuticals, Inc. Barr denies the remaining allegations of paragraph 9 of the Complaint.

10. Barr does not contest in this action that this Court has personal jurisdiction over Barr Laboratories, Inc. Barr denies the remaining allegations of paragraph 10 of the Complaint.

11. The allegations of paragraph 11 of the Complaint state a legal conclusion to which no response is required. Barr admits that Plaintiffs purport to base their choice of venue on 28 U.S.C. §§ 1391(b),(c) and (d), and 1400(b) and does not contest venue in this action.

12. Barr admits that U.S. Patent No. 5,464,632 (the "'632 patent") is entitled "Rapidly Disintegrable Multiparticular Tablet", recites on its face Gerard Cousin, Etienne Bruna, and Edouard Gendrot as named inventors, and that it states on its face that it issued on November 7, 1995. Barr admits that the USPTO issued a Reexamination Certificate for the '632 patent on February 21, 2001 and that a copy of the '632 patent with the Reexamination Certificate is attached as Exhibit A. Barr lacks knowledge and information sufficient to form a basis as to the remaining allegations of paragraph 12 of the Complaint, and therefore denies them.

13. Barr admits that U.S. Patent No. 6,328,944 (the "'944 patent") is entitled "Orally Disintegrable Tablets," recites on its face Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata as named inventors, and states on its face that it issued on December 11, 2001. Barr admits that a copy of the '944 patent is attached as Exhibit B. Barr lacks knowledge and information sufficient to form a belief as to the remaining allegations of paragraph 13 of the Complaint, and therefore denies them.

14. On information and belief, Barr admits that the FDA approved New Drug Application ("NDA") No. 21-428 for lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg, on August 30, 2002. Barr lacks knowledge and information sufficient to form a belief as to the remaining allegations of paragraph 14 of the Complaint, and therefore denies them.

15. Barr admits that the '632 and '944 patents are listed in the Orange Book for lansoprazole delayed release orally disintegrating tablets. Barr lacks knowledge and information

sufficient to form a belief as to the remaining allegations of paragraph 15 of the Complaint, and therefore denies them.

16. Barr denies the allegations of paragraph 16 of the Complaint.

17. Barr denies the allegations of paragraph 17 of the Complaint.

18. Barr denies the allegations of paragraph 18 of the Complaint.

19. Barr admits that Barr Laboratories, Inc. filed an ANDA seeking approval to market lansoprazole delayed release orally disintegrating tablets after concluding that it was appropriate to do so. Barr otherwise denies the allegations of paragraph 19 of the Complaint.

20. Barr denies the allegations of paragraph 20 of the Complaint.

21. Barr admits the allegations of paragraph 21 of the Complaint.

22. Barr admits the allegations of paragraph 22 of the Complaint.

23. Barr denies the allegations of paragraph 23 of the Complaint.

24. Barr denies the allegations of paragraph 24 of the Complaint.

25. The allegations of paragraph 25 of the Complaint state a legal conclusion to which no response is required. Barr lacks knowledge and information sufficient to form a belief as to the allegations of paragraph 25 of the Complaint, and therefore denies them.

26. Barr admits that Barr Laboratories, Inc. continues to seek approval of ANDA No. 90-152. Barr denies the remaining allegations of paragraph 26 of the Complaint.

27. Barr repeats and reasserts the response to each allegation set forth in paragraph 1 through 26 as if fully set forth herein.

28. Barr denies the allegations of paragraph 28 of the Complaint.

29. Barr denies the allegations of paragraph 29 of the Complaint.

30. Barr admits that Barr Laboratories, Inc. was aware of the existence of the '632 patent prior to filing ANDA No. 90-152. Barr denies the remaining allegations of paragraph 30 of the Complaint.

31. Barr denies the allegations of paragraph 31 of the Complaint.

32. Barr denies the allegations of paragraph 32 of the Complaint.

33. Barr denies the allegations of paragraph 33 of the Complaint.

34. Barr repeats and reasserts the response to each allegation set forth in paragraph 1 through 33 as if fully set forth herein.

35. Barr denies the allegations of paragraph 35 of the Complaint.

36. Barr denies the allegations of paragraph 36 of the Complaint.

37. Barr denies the allegations of paragraph 37 of the Complaint.

38. Barr denies the allegations of paragraph 38 of the Complaint.

39. Barr denies the allegations of paragraph 39 of the Complaint.

40. Barr repeats and reasserts the response to each allegation set forth in paragraph 1 through 39 as if fully set forth herein.

41. Barr denies the allegations of paragraph 41 of the Complaint.

42. Barr denies the allegations of paragraph 42 of the Complaint.

43. Barr admits that Barr Laboratories was aware of the '944 patent prior to filing ANDA No. 90-152. Barr denies the remaining allegations of paragraph 43 of the Complaint.

44. Barr denies the allegations of paragraph 44 of the Complaint.

45. Barr denies the allegations of paragraph 45 of the Complaint.

46. Barr denies the allegations of paragraph 46 of the Complaint.

47. Barr repeats and reasserts the response to each allegation set forth in paragraph 1 through 46 as if fully set forth herein.

48. Barr denies the allegations of paragraph 48 of the Complaint.

49. Barr denies the allegations of paragraph 49 of the Complaint.

50. Barr denies the allegations of paragraph 50 of the Complaint.

51. Barr denies the allegations of paragraph 51 of the Complaint.

52. Barr denies the allegations of paragraph 52 of the Complaint.

DEFENSES

FIRST DEFENSE
(Non-infringement of the '632 Patent)

53. The manufacture, use, sale, offer for sale, or importation into the United States of lansoprazole delayed release orally disintegrating tablets made according to ANDA 90-152 will not infringe any valid, enforceable claim of the '632 patent.

SECOND DEFENSE
(No Inducement of Infringement of the '632 Patent)

54. Barr Pharmaceuticals, Inc. has not induced, is not inducing, and will not induce infringement of the claims of the '632 patent.

THIRD DEFENSE
(Invalidity of the '632 Patent)

55. The claims of the '632 patent are invalid for failure to comply with one or more of the conditions for patentability as specified in Title 35 U.S.C. §§ 1 *et seq.*

FOURTH DEFENSE
(Non-infringement of the '944 Patent)

56. The manufacture, use, sale, offer for sale, or importation into the United States of lansoprazole delayed release orally disintegrating tablets made according to ANDA 90-152 will not infringe any valid, enforceable claim of the '944 patent.

FIFTH DEFENSE
(No Inducement of Infringement of the '944 Patent)

57. Barr Pharmaceuticals, Inc. has not induced, is not inducing, and will not induce infringement of the claims of the '944 patent.

SIXTH DEFENSE
(Invalidity of the '944 Patent)

58. The claims of the '944 patent are invalid for failure to comply with one or more of the conditions for patentability as specified in Title 35 U.S.C. §§ 1 *et seq.*

SEVENTH DEFENSE
(Failure to State a Claim)

59. The Complaint fails to state a claim against the Defendants upon which relief may be granted.

EIGHTH DEFENSE
(Lack of Standing)

60. The Plaintiffs lack standing to sue on the '632 patent, and assert the First and Second Claims for Relief alleged in their Complaint.

NINTH DEFENSE
(Lack of Subject Matter Jurisdiction)

61. The Complaint fails to establish subject matter jurisdiction over Barr Pharmaceuticals, Inc.

COUNTERCLAIM FOR DECLARATORY JUDGMENT

Jurisdiction and Venue

62. This counterclaim by Barr Laboratories, Inc. ("Counterclaimant") arises under the Declaratory Judgment Act and the Patent Laws of the United states, more particularly under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 1 *et seq.*, respectively. This Court has subject matter jurisdiction pursuant to 29 U.S.C. §§ 1338 and 2201. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by the Counterdefendants' choice of forum.

63. Actual and justiciable controversy exists between Counterclaimant and Counterdefendants as to the infringement and validity of the patents in suit, as evidenced, *inter alia*, by the Complaint and Answer in this action.

The Parties

64. Barr Laboratories, Inc. is a Delaware corporation with a place of business at 223 Quaker Road, Pomona, New York 10970.

65. Upon information and belief, based on the allegation in the Complaint, Takeda Pharmaceutical Company Limited is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

66. Upon information and belief, based on the allegation in the Complaint, TAP Pharmaceutical Products Inc. ("TAP") is a Delaware corporation, having a principal place of business at 675 North Field Drive, Lake Forest, Illinois.

The Controversy

67. Upon information and belief the '944 patent was issued by the USPTO on December 11, 2001.

68. Upon information and belief, and based upon the allegations in the Complaint, Takeda is the record owner of the '944 patent.

69. Upon information and belief and based upon the allegations in the Complaint, TAP is the exclusive licensee of the '944 patent.

70. Barr Laboratories submitted ANDA 90-152 with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial manufacture, use, sale, offer for sale, and importation into the United States of generic lansoprazole delayed-release orally disintegrating tablets containing 15 and 30 mg of lansoprazole prior to the expiration of the '944 patent.

71. ANDA 90-152 contains a statement that in the applicant's opinion and to the best of its knowledge, the '944 patent is invalid, unenforceable, and/or not infringed by the manufacture, use, sale, offer for sale, or importation into the United States of applicant's lansoprazole delayed release orally disintegrating tablets.

72. In a letter dated April 24, 2008, applicant notified Takeda and TAP that the FDA had received an ANDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(Vii)(IV). This letter was delivered to the Counterdefendants.

COUNT I

Declaratory Judgment of Non-Infringement of the '944 Patent

73. Barr repeats and reasserts paragraphs 62 through 72 as if set forth specifically here.

74. The manufacture, use, sale, offer for sale, or importation into the United States of lansoprazole delayed-release orally disintegrating tablets made pursuant to ANDA no. 90-152 shall not constitute infringement of the '944 patent.

COUNT II

Declaratory Judgment of Invalidity of the '944 Patent

75. Barr repeats and reasserts paragraphs 62 through 74 as if set forth specifically here.

76. The claims of the '944 patent are invalid for failure to comply with the conditions for patentability as specified in Title 35 U.S.C. §§ 1 *et seq.*

PRAYER FOR RELIEF

WHEREFORE, Counterclaimants pray the Court enter judgment against Plaintiffs:

A. Denying all relief sought in the Complaint and dismissing the Complaint with prejudice;

B. Declaring the claims of the '632 patent are invalid;

C. Declaring the claims of the '632 patent are not, and will not be, infringed by the manufacture, use, sale, offer for sale, and/or importation of lansoprazole delayed release orally disintegrating tablets pursuant to ANDA 90-152;

D. Declaring that Barr Pharmaceuticals, Inc. has not and will not induce infringement of any claims of the '632 patent.

E. Enjoining Plaintiffs/Counterdefendants, their assigns, and all those in privity therewith from asserting the '632 patent against Defendants/Counterclaimant or any of their customers or suppliers;

F. Declaring the claims of the '944 patent are invalid;

G. Declaring the claims of the '944 patent are not, and will not be, infringed by the manufacture, use, sale, offer for sale, and/or importation of lansoprazole delayed release orally disintegrating tablets pursuant to ANDA 90-152;

H. Declaring that Barr Pharmaceuticals, Inc. has not and will not induce infringement of any claim of the '944 patent;

I. Enjoining Plaintiffs/Counterdefendants, their assigns, and all those in privity therewith from asserting the '944 patent against Defendants/Counterclaimant or any of their customers or suppliers;

J. Declaring that Plaintiffs lack standing to sue on the '632 patent and dismissing all claims related to the '632 patent;

K. Declaring that there is no subject matter jurisdiction over Barr Pharmaceuticals, Inc.

L. Awarding Defendants/Counterclaimant their attorneys' fees pursuant to 35 U.S.C. § 285, and their costs and expenses; and

M. Awarding Defendants/Counterclaimant such other and further relief as may be just and proper.

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Dated: June 30, 2008
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CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on June 30, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on June 30, 2008, the attached document was Electronically Mailed to the following person(s):

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